REMARKS

Status of the Claims

Claims 1, 2, 5-16 and 20-26 are currently pending in the application. Claims 1-5 and 7 stand rejected. The Examiner objects to claims 1-5 and 7. Claims 6, 8-16 and 20-26 are withdrawn as being drawn to a non-elected invention. Claims 1, 2, 5 and 7 have been amended as set forth herein. Claims 3 and 4 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to claims 1 and 2 are supported by the specification at, for instance, page 7, lines 9-12. Reconsideration is respectfully requested.

Objections to the Claims

The Examiner objects to claims 1-5 and 7 as encompassing non-elected subject matter. (*See*, Office Action of May 18, 2006, at page 2, hereinafter, "Office Action"). Claims 3 and 4 have been cancelled herein without prejudice or disclaimer, thus obviating the objection of claims 3 and 4. Applicants traverse the objections as to the remaining claims as set forth hereinafter.

As amended, claim 1 is fully encompassed by the Examiner's Restriction Requirement, Group I, claims drawn to "an isolated polypeptide N-acetylglucosamine transferase and SEQ ID NO:1." Claim 1, as amended, recites, "An isolated protein having an amino acid sequence shown in SEQ ID NO: 1, or an amino acid sequence having a homology of not less than 95% to the amino acid sequence of SEQ ID NO:1, which has an activity to transfer *N*-acetylglucosamine to a non-reducing terminal of Galβ1-4Glc or Galβ1-4GlcNAc group through β1,3-linkage."

While claim 2 encompasses isolated polypeptides having an amino acid sequence according to SEQ ID NO:3, and while this species was not selected for initial examination, Applicants are not required to remove this subject matter until allowable subject matter has been identified. (*See*, M.P.E.P. § 808).

The Examiner also states that claim 2 fails to further limit the subject matter of claim 1, from which it depends. Claim 2 has been amended to recite, "The protein according to claim 1, which has the amino acid sequence shown in SEQ ID NO: 3, or wherein the amino acid sequence has a homology of not less than 95% to said amino acid sequence shown in SEQ ID NO:3." Thus, as amended, claim 2 further limits claim 1 because claim 1 is directed to isolated polypeptides having the amino acid sequence of SEQ ID NO:1 or those having 95% homology to SEQ ID NO:1. Claim 2 is directed to isolated polypeptides having the amino acid sequence of SEQ ID NO:3. The amino acid sequence SEQ ID NO:3 encompasses SEQ ID NO:1 and includes additional amino acids not found in SEQ ID NO:1. Thus, amended claim 2 further limits the scope of claim 1.

The Examiner states that claim 5 fails to further limit the subject matter of the claim from which it depends. (*Id.*). However, claim 5 is in fact narrower than claim 1 or 2. SEQ ID NO:1 recited in claim 1 has 283 amino acids. SEQ ID NO:3 recited in claim 2 has 327 amino acids. The homology in claim 1 is restricted to not less than 95%. Thus, at most, there may be substitution of 5% of the sequence, or deletion of 5%, or insertion or addition. Five percent of 283 amino acids is equivalent to 14 amino acids. Thus, claims 1 and 2 encompass substitutions, deletions, insertions or additions of up to 14 amino acids. In contrast, claim 5 recites that SEQ ID NO:1 may have one to several substitutions. The term "several" is interpreted to mean, at

most, 9 amino acids, and is obviously less than 14 amino acids, as required by claims 1 and 2. Therefore, claim 5 is narrower than claim 1 or 2, and further limits the phrase "homology of not less than 95%."

The Examiner further states that claim 7 is also indefinite for failing to further limit the subject matter of the claim from which it depends. Claim 7 depends from claims 1 or 2, and is directed to a protein that comprises a region of residues that have the amino acid sequences according to claims 1 or 2. Thus, since claim 7 encompasses amino acid sequences that have more residues than SEQ ID NOS:1 or 3, claim 7 is narrower than either claims 1 or 2.

Reconsideration and withdrawal of the objections to claims 1, 2, 5 and 7 are respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1, 2 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. (*See*, Office Action, at pages 3-4). Applicants traverse the rejection as set forth herein.

The Examiner states that the specification only discloses the structure of three representative species of the isolated polypeptides encompassed by claim 1 and that the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding a polypeptide having activity to transfer *N*-acetylglucosamine to a non-reducing terminal of Galβ1-4Glc or Galβ1-4GlcNAc group through β1,3-linkage. (*Id.* at page 4).

Although Applicants do not agree that claim 1 lacks written description support in the as-filed specification, to expedite prosecution, claim 1 has been amended to recite, "An isolated protein having an amino acid sequence shown in SEQ ID NO: 1, or an amino acid sequence having a homology of not less than 95% to the amino acid sequence of SEQ ID NO:1, which has an activity to transfer *N*-acetylglucosamine to a non-reducing terminal of Galβ1-4Glc or Galβ1-4GlcNAc group through β1,3-linkage." Thus, as amended, claim 1 no longer recites "any polypeptide having one or more amino acids substituted or deleted or inserted or added to SEQ ID NO:1," a basis for the present rejection. Furthermore, consistent with the Written Description Guidelines, claim 1 has been amended to recite only those isolated polypeptides having an amino acid sequence according to SEQ ID NO:1 or an amino acid sequence having at least 95% homology to SEQ ID NO:1.

Thus, at least as amended, claim 1 fully satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, as further clarified by the Written Description Guidelines.

Additionally, although Applicants do not agree that claim 2 fails to satisfy the written description requirement, to expedite prosecution, claim 2 has been similarly amended and no longer recites the phrase which at least in part forms the basis of the Examiner's rejection of claim 2. Furthermore, claim 2 has been amended to encompass only those isolated polypeptides having an amino acid sequence according to SEQ ID NO:3 or an amino acid sequence having at least 95% homology to SEQ ID NO:3. The sequence of SEQ ID NO:3 is related to SEQ ID NO:1 in that SEQ ID NO:3 encodes SEQ ID NO:1 plus some additional amino acids.

Support for these amendments may be found throughout the as-filed specification at, for instance, page 7, line 12.

Claim 7 depends from claims 1 or 2 and thus incorporates all of the limitations of these claims. Therefore, the same arguments as presented for claims 1 and 2 may also be applied to claim 7. That is, claim 7 also does not lack written description support because claim 7 also does not recite the phrase upon which the Examiner bases the present rejection.

Reconsideration and withdrawal of the written description rejection of claims 1, 2 and 7 are respectfully requested.

Enablement

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at page 5). Claims 3 and 4 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claims 3 and 4. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that the specification does not provide enablement for any polypeptide having 70% or 90% sequence homology to SEQ ID NO:1 or a polypeptide in which one or more amino acids are substituted, deleted, inserted or added to SEQ ID NO:1. (*Id.*). The Examiner refers to the unpredictability of protein structure and function relationships and provides additional reasoning for the basis of the rejection at page 6, second paragraph of the Office Action marked as (A)-(D). (*Id.* at page 6).

Although Applicants do not agree that claim 1 lacks enablement in the as-filed specification, to expedite prosecution, claim 1 has been amended to recite, "An isolated protein having an amino acid sequence shown in SEQ ID NO: 1, or an amino acid sequence having a homology of not less than 95% to the amino acid sequence of SEQ ID NO:1, which has an

activity to transfer *N*-acetylglucosamine to a non-reducing terminal of Galβ1-4Glc or Galβ1-4GlcNAc group through β1,3-linkage." Thus, as amended, claim 1 no longer recites "any polypeptide having one or more amino acids substituted or deleted or inserted or added to SEQ ID NO:1," as asserted by the Examiner as one of the bases for the present rejection. Furthermore, claim 1 has been amended to recite only those isolated polypeptides having an amino acid sequence according to SEQ ID NO:1 or an amino acid sequence having at least 95% homology to SEQ ID NO:1.

Thus, at least as amended, claim 1 fully satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph.

Additionally, although Applicants do not agree that claim 2 fails to satisfy the enablement requirement, to expedite prosecution, claim 2 has been similarly amended and no longer recites the phrase which at least in part forms the basis of the Examiner's rejection of claim 2. Furthermore, claim 2 has been amended to encompass only those isolated polypeptides having an amino acid sequence according to SEQ ID NO:3 or an amino acid sequence having at least 95% homology to SEQ ID NO:3. The sequence of SEQ ID NO:3 is related to SEQ ID NO:1 in that SEQ ID NO:3 encodes SEQ ID NO:1 plus some additional amino acids.

Claim 5 depends from claim 1 or claim 2. Claim 7 also depends from claim 1 or claim 2. Thus claims 5 and 7 both incorporate all of the limitations of the claims from which they depend, individually. In other words, claims 5 and 7 are limited by the 95% homology of SEQ ID NOS:1 and 3 as recited in claims 1 and 2. Therefore, claims 5 and 7 are also fully enabled by the as-filed specification for the same reasons given above with respect to claims 1 and 2.

Reconsideration and withdrawal of the enablement rejection of claims 1, 2, 5 and 7 are respectfully requested.

Rejections Under 35 U.S.C. § 102(a)

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Kataoka et al., GenBank Accession No. AF502429 and AAM61770 (hereinafter referred to as "Kataoka et al."). (*See*, Office Action, at page 8). Claims 3 and 4 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claims 3 and 4. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Kataoka et al. disclose a human cDNA which encodes a protein having 401 amino acid residues which are 100% identical to SEQ ID NO:1 and that the polypeptide so encoded has the activity to transfer beta-1,3-*N*-acetylglucosamine groups through a beta-1,3-linkage. (*Id.* at page 9). The Examiner further states that Applicants cannot rely on their foreign priority claim to overcome this rejection because a verified English language translation of the priority document has not been made of record. (*Id.*).

Attached hereto and submitted herewith is a verified English language translation of the foreign priority document, thus obviating the present rejection of claims 1, 2, 5 and 7 based on Kataoka et al.

Rejections Under 35 U.S.C. § 102(b)

Piller et al., *J. Biol. Chem.*, 258(20):12293-12299, 1983

Claims 1, 2 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Piller et al., *J. Biol. Chem.*, 258(20):12293-12299, 1983 (hereinafter referred to as "Piller et al."). (*See*, Office Action, at page 8). Applicants traverse the rejection as set forth herein.

The Examiner states that Piller et al. disclose an enzyme which is human and has an activity similar to the activity that the presently claimed isolated polypeptides possess. (*Id.*).

However, Piller et al. do not disclose any amino acid sequences that encode the disclosed activity. Thus, Piller et al. cannot anticipate the presently claimed invention, at least with respect to claim 1, since Piller et al. do not disclose each and every element of the presently claimed invention. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*See*, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Dependent claims 2 and 7 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2 and 7 are respectfully requested.

Togayachi et al., *J. Biol. Chem.*, 276(205):22032-22040, 2001

Claims 1, 2 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Togayachi et al., *J. Biol. Chem.*, 276(205):22032-22040, 2001 (hereinafter referred to as

"Togayachi et al."). (*See*, Office Action, at page 8). Applicants traverse the rejection as set forth herein.

The Examiner states that Togayachi et al. disclose the cloning of a human enzyme having a similar activity to that which the presently claimed isolated polypeptides possess. (*Id.*).

However, the enzyme disclosed in Togayachi et al. is only 50% homologous to SEQ ID NO:1. As already discussed, above, claim 1 has been amended to recite, "An isolated protein having an amino acid sequence shown in SEQ ID NO: 1, or an amino acid sequence having a homology of not less than 95% to the amino acid sequence of SEQ ID NO:1, which has an activity to transfer *N*-acetylglucosamine to a non-reducing terminal of Galβ1-4Glc or Galβ1-4GlcNAc group through β1,3-linkage." Thus, the enzyme of Togayachi et al. cannot anticipate the presently claimed invention, at least according to claim 1, because the enzyme of Togayachi et al. is not at least 95% homologous to SEQ ID NO:1, as required by presently amended claim 1.

Dependent claim 2 and 7 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2 and 7 are respectfully requested.

Rejections Under 35 U.S.C. § 102(e)

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lal et al., WO 02/26950 (hereinafter referred to as "Lal et al."). (*See*, Office Action, at page 8). Claims 3 and 4 have been cancelled herein without prejudice or disclaimer, thus obviating the

rejection as to claims 3 and 4. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that Lal et al. disclose a human glycosyltransferase enzyme having 401 amino acids that are 99.9% identical to SEQ ID NO:1. (*Id.*). However, the Examiner states that the enzyme of Lal et al. does not disclose whether it has the same activity as recited in presently amended claim 1. (*Id.*). The Examiner states that such enzymatic activity would be an inherent property of Lal et al. based on the high degree of identity between its sequence and that of SEQ ID NO:1.

The disclosure of Lal et al. depends entirely on bioinformatic analyses using computer software and existing data bases of genomes, ESTs and etc. Lal et al. do not disclose performing any experiment to isolate any protein or characterize the activity of a protein.

In contrast, claim 1, as amended, recites "an isolated protein." Since Lal et al. did not isolate any protein, at least for this reason, claim 1 can not be anticipated by the disclosure of Lal et al.

Furthermore, it is established in the U.S., Europe and Japan, as well as in other developed countries, that one cannot patent simply a sequence of a protein without any understanding or proof of the function of that protein which is required to establish utility of the protein. It is further noted that the international application of Lal et al. has been pending for over 5 years and yet has not been allowed in any country in the world. This may indicate that the disclosure of Lal et al. is not patentable for this very reason.

One must first isolate or purify the protein to allow experimental determination of the utility of the protein, *i.e.* to determine its activity or mechanism of action or biological function.

However, isolating proteins present in only trace amounts in nature is exceedingly difficult. In spite of such challenges, the present Inventors have successfully accomplished this difficult task by isolating the protein and determining its function. Thus, at least for this additional reason, the present invention, as recited in claim 1, cannot be anticipated by the disclosure of Lal et al.

Dependent claims 2, 5 and 7 are not anticipated as, *inter alia*, depending from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 2, 5 and 7 are respectfully requested.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Attachment:
Verified English Language Translation of Japanese Patent Application No. 2002-70996